NOT FOR PUBLICATION **UNDER SEAL**

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JANSSEN PRODUCTS, L.P., et al.,	:	
Plaintiffs,	:	**OPINION**
v.	:	Civ. No. 10-5954 (WHW)
LUPIN LIMITED, et al.,	:	**FILED UNDER SEAL**
Defendants.	:	

Walls, Senior District Judge

In this patent infringement suit, Defendants Lupin Limited and Lupin Pharmaceuticals, Inc. ("Lupin"), with Defendants Mylan Pharmaceuticals, Inc. and Mylan, Inc. ("Mylan") (collectively, "Defendants"), move under Fed. R. Civ. P. 60(b), or, in the alternative, Rule 59(e), to modify this Court's Injunction Order of August 14, 2014 (ECF No. 944). Plaintiffs Janssen Products, L.P. and Janssen R&D Ireland ("Plaintiffs") oppose Defendants' motion.

Deciding the motion without oral argument under Fed. R. Civ. P. 78, and finding no circumstances that would justify any modification of its Order, this Court denies Defendants' motion.

FACTUAL AND PROCEDURAL BACKGROUND

Because the facts of the case are presented thoroughly in the Court's recent Opinion, ECF No. 943, the Court will only provide the immediate background here. On August 14, 2014, following a bench trial, the Court issued Opinion, ECF No. 943, and Order, ECF No. 944, finding patent infringement by the Defendants, and granting Plaintiffs' request for a permanent

injunction barring Defendants from importing into the United States their ANDA products and selling them. ECF No. 944 at ¶¶ 1-4. The Court also issued an order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Lupin's ANDA be no earlier than the day after the expiration of the '645 Patent and any associated exclusivity. *Id.* at ¶¶ 5-7.

Defendants now move to modify four paragraphs of the Court's Order: 2, 4, 6 and 7. Defendants offer a marked-up revision in their brief, Def.'s Br. at 2-4, which is loosely summarized here. To paragraphs 2 and 4, Defendants would make two changes. *Id.* at 2-3. First, they would add the adjective "commercial" to modify "products." *Id.* Second, they would insert additional references to claim and patent numbers. *Id.* As to paragraphs 6 and 7, Defendants would have the text read that the injunction is related to darunavir tablets "made using darunavir ethanolate in a darunavir/ethanol ratio of approximately 1:1 or any colorable variation thereof." *Id.* at 3-4. Their edited version would also insert the word "commercial" into paragraphs 6 and 7, and add the words, "claim 4," directly after "the expiration of" and before "the '645 Patent." *Id.*

DISCUSSION

Standard of Review

Fed. R. Civ. P. 60(b) allows a court to provide relief from a judgment or order when, among other things, "applying the judgment order prospectively is no longer equitable" (subsection (b)(5)), or "for any other reason that justifies relief" (subsection (b)(6)). The Court's power to grant relief under this rule is narrow. "Due to the overriding interest in the finality and repose of judgments, a Rule 60(b) motion is considered extraordinary relief which should be granted only where extraordinary justifying circumstances are present." *Katz v. Twp. of Westfall*, 287 Fed. Appx. 985, 988 (3d Cir. 2008) (quotations and citations omitted).

When a party moves for reconsideration under Fed. R. Civ. P. 59(e), the scope will be determined by the basis for the motion, such as a claim that reconsideration is justified by an intervening change in controlling law. *See North River Ins. Co. v. CIGNA Reinsurance Co.*, 52 F.3d 1194, 1218 (3d Cir. 1995). The Rule 59(e) motion may not be used to relitigate old matters. *See Gutierrez v. Ashcroft*, 289 F. Supp. 2d 555, 561 (D.N.J. 2003) ("A party seeking reconsideration must show more than a disagreement with the Court's decision, and recapitulation of the cases and arguments considered by the court before rendering its original decision fails to carry the moving party's burden." (citation and quotation omitted)). A motion under Fed. R. Civ. P. 59(e) "must rely on one of three grounds: (1) an intervening change in controlling law; (2) the availability of new evidence; or (3) the need to correct clear error of law or prevent manifest injustice." *Lazaridis v. Wehmer*, 591 F.3d 666, 669 (3d Cir. 2010) (citations omitted).

Standard for Granting a Permanent Injunction

The standard for granting a permanent injunction, and the rationale for doing so in this case, are described in the Court's Opinion. ECF No. 943 at 72-99. In short, a plaintiff must demonstrate (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction. *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 393-94 (2006). Ultimately, the "decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts." *Id.*

Fed. R. Civ. P. 65 governs injunctions, with subsection (d) setting forth specificity requirements. *See Int'l Rectifier Corp. v. IXYS Corp.*, 383 F.3d 1312, 1316 (Fed. Cir. 2004).

"The rule requires an injunction to prohibit only those acts sought to be restrained, which in this case are infringement of the patent by the devices adjudged to infringe and infringement by devices no more than colorably different therefrom." *Id.* at 1317. The Federal Circuit further described the requirements of Rule 65:

> In the patent infringement context, this court has rejected as overly broad a permanent injunction that simply prohibits future infringement of a patent . . . . [W]e vacated an injunction that "forever barred" the adjudged infringer from infringing the patent at issue. That injunction failed to satisfy the requirements of Rule 65(d) because it lacked specific terms and a reasonably detailed description of the acts sought to be restrained. Furthermore, the order failed to state which acts constituted infringement or to expressly limit its prohibition to the manufacture, use, or sale of the specific device found to infringe, or devices no more than colorably different from the infringing device. *Id.* at 1316 (internal citations omitted).

35 U.S.C. § 271(g) declares, in relevant part, that "[w]hoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent."

Analysis

It is unnecessary to decide whether Defendants move under Rule 59 or Rule 60. No matter that they are asking the Court to "prevent manifest injustice" under Rule 59(e) or asking for relief under Rule 60 because "applying the judgment order prospectively is no longer equitable," the thrust of their argument is the same: they claim that the injunction is overly broad. They would liken this injunction to the one the Federal Circuit modified in *International Rectifier*. 383 F.3d at 1315-18.

Defendants do not convince the Court that the injunction is too broad, vague or inequitable. The Order uses language from 35 U.S.C. § 271(g), and is modeled after injunctions

previously upheld in similar cases. As example, a district court issued this one in a case involving some of the same litigants, and the Federal Circuit upheld it shortly after its decision in *International Rectifier*:

> "[t]he effective date of any approval of Mylan's ANDA product shall be no earlier than the date of the expiration of the '580 patent family. The Defendants are enjoined from making, using, offering to sell, selling within the United States or importing into the United States the fentanyl transdermal patches described in ANDA No. 76–258."

Alza Corp. v. Mylan Labs., Inc., 310 F. Supp. 2d 610, 637 (D. Vt. 2004), *aff'd*, 391 F.3d 1365 (Fed. Cir. 2004). There the language did not include the word "commercial"—which was not necessary—§ 271(g) does not require it—or specify the claim number. Here paragraphs 1, 3 and 5 of the injunction specify which claims are valid and infringed. Paragraphs 2, 4 and 6 complement them by specifying the injunctive remedy ordered by the Court. The injunction plainly details what the infringement was and how it should be restrained. Any reasonable reader would find that such plain, direct language easily satisfies the requirements of Rule 65.

Defendants further contend that the Order enjoins them from importing into the United States, making, using, or selling a product found in claims the patentee voluntarily dismissed with prejudice, thus ignoring *International Rectifier*'s admonition that an injunction should apply only to those devices adjudicated and those no more than colorably different from them. Def.'s Reply at 8; 383 F.3d at 1317. Their interpretation is incorrect. As to the '015 and '411 patents, the injunction is specifically directed to the issues contested at trial. The injunction cites to Lupin's ANDA (ANDA 202073) and Mylan's ANDA (ANDA 202136), the infringing aspects of which were clearly defined in the trial opinion. *See, e.g.*, Dkt. 943 at 5 (specifying the ANDAs at issue); *id.* at 5-6 (defining the claim of the '015 patent at issue); *id.* at 10-11 (defining the claim of the '411 patent at issue). As to the '645 patent, the related sections of the injunction were written in accordance with § 271(e)(4)(A), and properly reference Lupin's ANDA. Dkt. No. 943

at 98-99. The injunction makes clear that Lupin is enjoined until the day after the expiration of the '645 patent from the enumerated activities related to the tablets described in the ANDA or "any darunavir product that includes darunavir ethanolate in a darunavir/ethanol ratio of approximately 1:1 or any colorable variation thereof." Order of August 14, 2014 at ¶ 7. The injunction protects the subject matter of the patent; "Prezista is a pharmaceutical composition of a 1:1 ethanolate form of darunavir, exactly as claimed in the '645 Patent." Dkt. No. 943 at 65. With the scope of the injunction clear, specific, and justified by statute, there is no reason to alter the text. "Simply put, we read the injunction to contain the very limitations [the defendant] now seeks." *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1293 (Fed. Cir. 2012) *cert. denied*, 132 S. Ct. 2442 (2012).

CONCLUSION

Defendants' motion is denied.

October 7, 2014

IT IS SO ORDERED:

William H. Walls, U.S.D.J.

United States Senior District Judge